

## REMARKS

Claims 6-14 and 21-32 are pending in this Application, with claims 6, 9 and 24 being independent claims. Claim 33 is new. No new matter has been added by these amendments.

Claims 6-14 and 21-32 stand rejected under 35 U.S.C. § 101. Claims 6-13 and 21-32 stand rejected under 35 U.S.C. § 102(b). Claim 14 stands rejected under 35 U.S.C. § 103. These rejections are traversed for the reasons below.

### The Claims include Eligible Subject Matter

Claims 6-14 and 21-32 stand rejected under 35 U.S.C. § 101 for claiming an unpatentable body part. In particular, the Examiner states that various claims “positively recites part of a human,” and thus the claims “include a human within their scope and are non-statutory.” This rejection is traversed for the reasons below.

Section 2105 of M.P.E.P. states that the “Office will decide the questions as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in *Chakrabarty*, e.g., that ‘a nonnaturally occurring manufacture or composition of matter’ is patentable, etc” (emphasis added) (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)). Section 2105 further states that “[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. 101 must be made” (emphasis added).

The Applicants respectfully disagree with the Examiner’s construction of this section of the M.P.E.P. and the underlying case law including *In re Wakefield*. The M.P.E.P. does not mandate a rejection under 35 U.S.C. § 101 if a claim “positively recites part of a human.” Rather, Section 2105 of the M.P.E.P. relates to a claimed invention that “encompasses a human being.” The Applicants believe this distinction is critical: many claimed inventions (e.g., prostheses constructed from human tissue, etc.) recite positively part of a human. Such claims, however, are still eligible for patenting because the claimed inventions do not actually “encompass a human being” even though they arguably “recite part of a human.”

This prohibition on a claim that “encompasses a human being” is best understood as a prohibition on claiming an entire human being at any stage of development (e.g., an entire

human or human embryo), not merely claiming something that happens to include a portion of a human being. This prohibition on a claim that “encompasses a human being” was a result of several court cases that were all directed to entire organisms: *Chakrabarty* related to a genetically altered bacterium capable of breaking down crude oil; *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 35 U.S. 124, 143-46 (2001) related to newly developed plant breeds; and *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Inter. 1987) related to an oyster that was chromosomally altered. *See also* Section 2105 of M.P.E.P. In light of the fact that these court cases held various organisms were eligible patentable subject matter, the Office’s prohibition was a clarification to these cases on patentable organisms and merely prohibited the patenting of entire human beings. The prohibition, however, is entirely silent as to claims that include only a portion of a human being.

The citation of *In re Wakefield* in the outstanding Office Action) is inapposite. *Wakefield* merely stands for the proposition that a claim can recite a negative limitation without running afoul of rejections under 35 U.S.C. § 112. *Wakefield* has nothing to do with subject matter eligible for patenting under 35 U.S.C. § 101, and appears to be entirely unrelated to statements in the Office Action for which *Wakefield* was cited.

Thus, the claims are directed to subject matter eligible for patenting and the Applicants respectfully request that the outstanding rejection under 35 U.S.C. § 101 be withdrawn.

#### The Claims are Patentable Over Caldarise

Claims 6-13 and 21-32 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,681,317 to Caldarise (the “Caldarise patent”). This rejection is traversed for the reasons below.

Independent claims 6 and 9 each recite “a first region of cancellous bone . . . being compressed” and “a second region of cancellous bone being substantially uncompressed cancellous bone.” The Office Action, however, refers to a compressed cancellous bone and an uncompressed cancellous bone with merely reference to Figure 2. At best, Figure 2 shows different chambers in which bone cement may be loaded. Figure 2, however, in no way discloses or suggests that one chamber contains compressed cancellous bone and the other chamber contains uncompressed cancellous bone. The Caldarise patent entirely fails to disclose

or suggest any differences between the cancellous bone in the two chambers. At best, the Caldarise patent discloses bone cements of different viscosities such that these bone cements are extruded from their respective chambers at different rates. Such different viscosities, however, do not relate to differences in compressed bone cement and uncompressed bone cement.

In addition, independent claim 24 recites “a region of cortical bone” where a first region of cancellous bone and a second region of cancellous bone are “native to the region of cortical bone.” Nothing in the Caldarise patent discloses or suggest any third region of bone, and nothing in the Office Action indicates that such recitations were considered.

Moreover, the Applicants respectfully disagree that the claims include statements of intended use or other functional statements. More specifically, the Examiner states in the Office Action that with “regards to statements of intended use and other functional statements do not impose any structural limitations on the claims.” While it is unclear to which recitations this asserts relates, at least the recitations discussed above (e.g., compressed cancellous bone, uncompress cancellous bone, a region of cortical bone, regions of cancellous bone native to the cortical bone, etc.) are plainly structural in nature. In other words, at least these recitations relate to the structure of recitation (compressed versus uncompressed) and the material of the recitation (cancellous bone versus cortical bone).

The Applicants respectfully submit that the selection of a component at different points of time, in a non-sequential manner, is improper and that the rejection should be withdrawn. For at least this reason, independent claims 6 and 9, and their dependent claims, are patentable over the Scholten patent. The Applicants respectfully request that the Examiner withdraw the outstanding rejection of claims 6 and 9 under 35 U.S.C. § 102(b).

#### The Claims are Patentable Over Caldarise in view of Shastri

Claim 14 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over the Caldarise patent in view of U.S. Patent 5,837,752 to Shastri (“the Shastri patent”). This rejection is traversed for the reasons below.

As discussed above, the Caldarise patent fails to anticipate independent claim 9. The Shastri patent fails to remedy any deficiencies in Caldarise. Thus, the Caldarise patent in view of the Shastri patent fails to disclose or suggest the recitations of independent claim 9. For at least

this reason, claim 9, and its dependent claim 14, are patentable over the Caldarise patent in view of the Shastri patent. The Applicants respectfully request that the Examiner withdraw the outstanding rejection of claim 14 under 35 U.S.C. § 103(a).

#### New Claim 33

New independent claim 33 recites “a region of cortical bone,” “a first region of cancellous bone native to the region of cortical bone . . . [and] compressed to define an at least a portion of a first cavity,” “a first region of bone filler material disposed within the first cavity . . . [and] defining at least a portion of a second cavity within the first cavity “a second region of bone filler material disposed within the second cavity,” “a second region of cancellous bone native to the region of cortical bone and being substantially uncompressed cancellous bone” and “the first region of bone filler material being disposed between the first region of cancellous bone and the second region of bone filler material.”

The cited references fail to disclose these recitations. Thus, independent claim 33 is patentable.

#### **CONCLUSION**

All rejections having been addressed, Applicants respectfully submit that the present application is in condition for allowance, and earnestly solicit a Notice of Allowance, which is believed to be in order. Should the Examiner have any questions regarding this communication, or the application in general, he is invited to telephone the undersigned.


The Director is hereby authorized to charge any appropriate fees under 37 CFR §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 50-1283.

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COOLEY GODWARD KRONISH LLP  
ATTN: Patent Group  
1200 19<sup>th</sup> Street, NW, 5<sup>th</sup> Floor  
Washington, DC 20036  
Tel: (703) 456-8000 or  
Fax: (202) 842-7899

Respectfully submitted,  
**COOLEY GODWARD KRONISH LLP**

By:

  
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Christopher R. Hutter  
Reg. No. 41,087